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(54) **TRANSRECTAL ULTRASOUND ABLATION PROBE**

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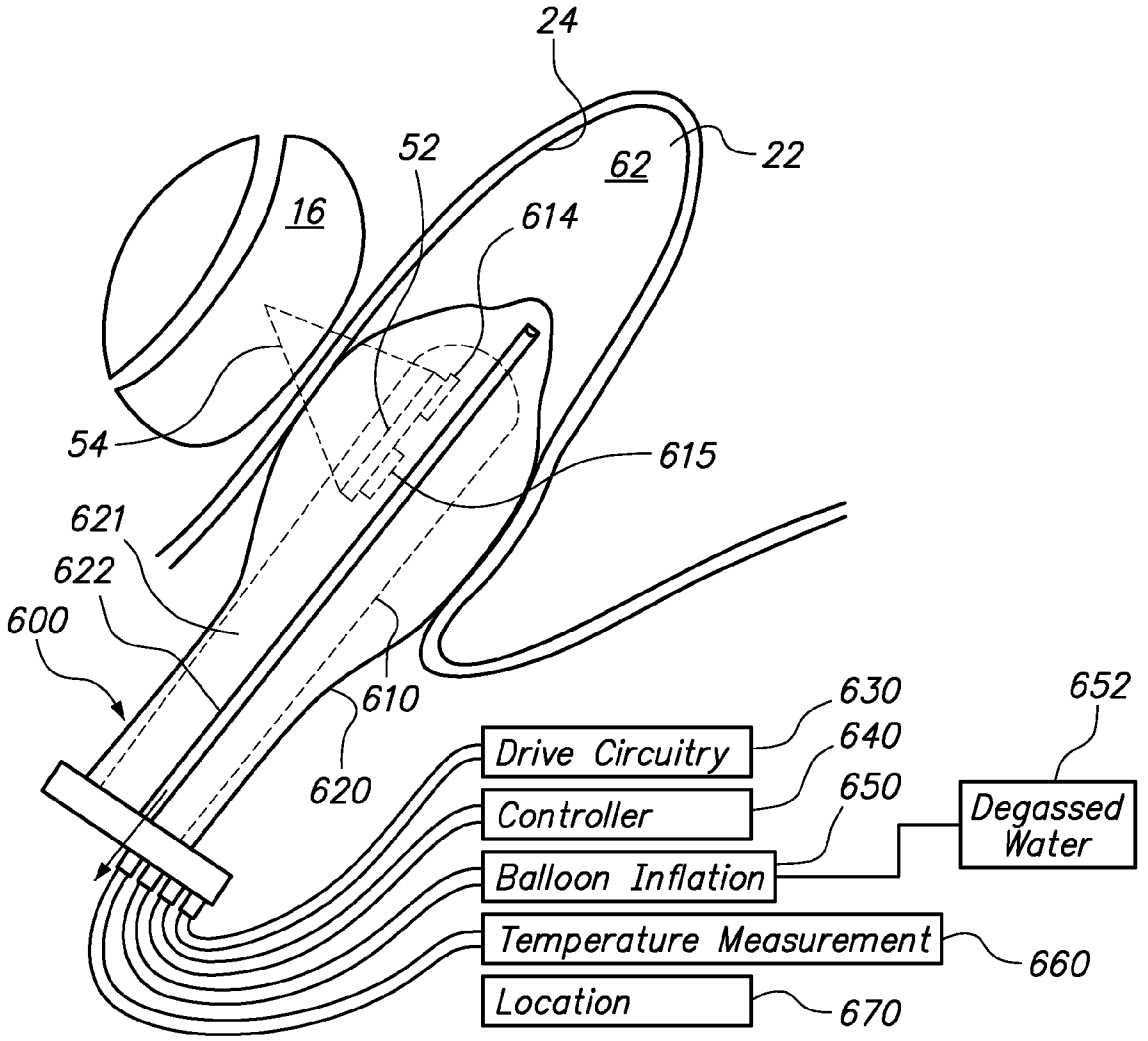
(57) **ABSTRACT**

Transrectal ultrasound probes, systems and related methods. A probe includes an anisotropic balloon that defines a cavity for receiving a probe body that carries an ultrasound transducer. A vent tube is attached to or integral with, an outer surface of the anisotropic balloon. The balloon is structured to have inflation and elasticity characteristics that allow air bubbles between the balloon and rectal wall to be pushed away to form an improved acoustic interface while allowing bowel gas to be vented through the vent tube.



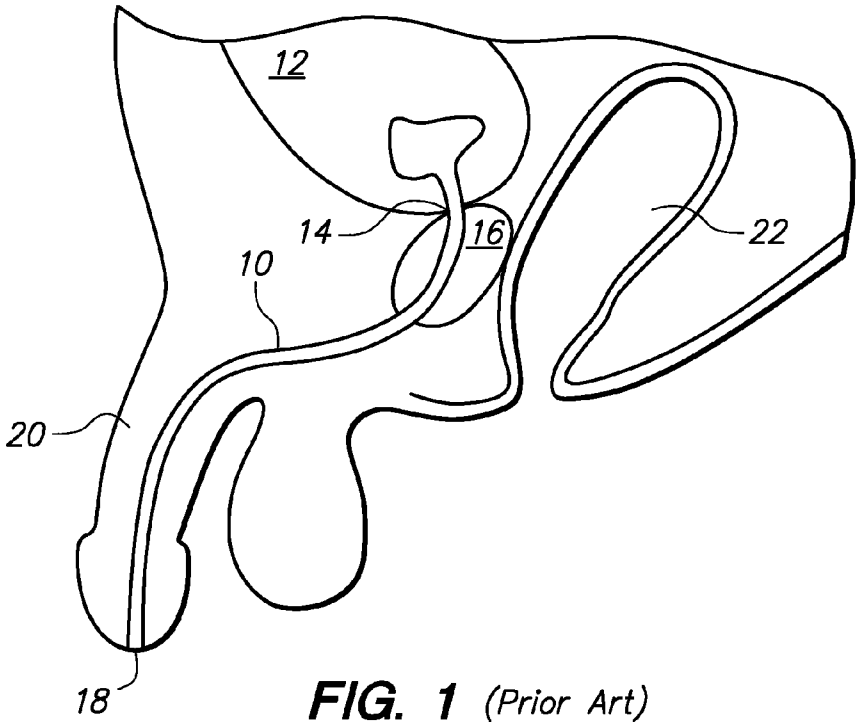


FIG. 1 (Prior Art)

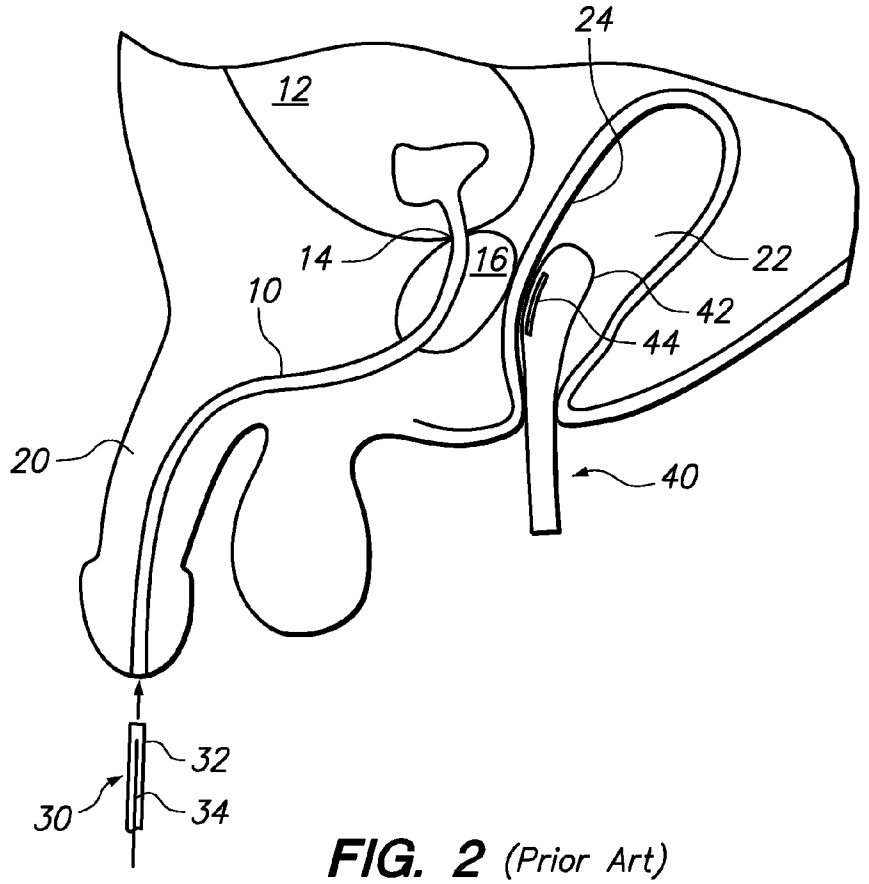


FIG. 2 (Prior Art)

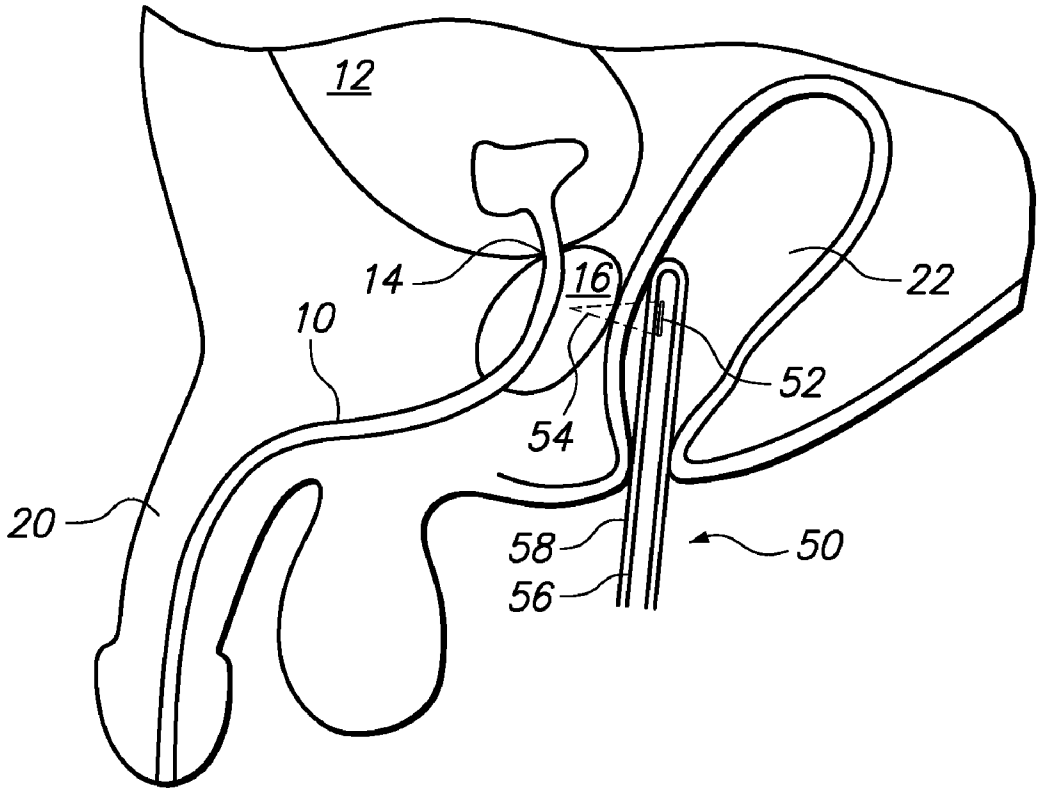


FIG. 3 (Prior Art)

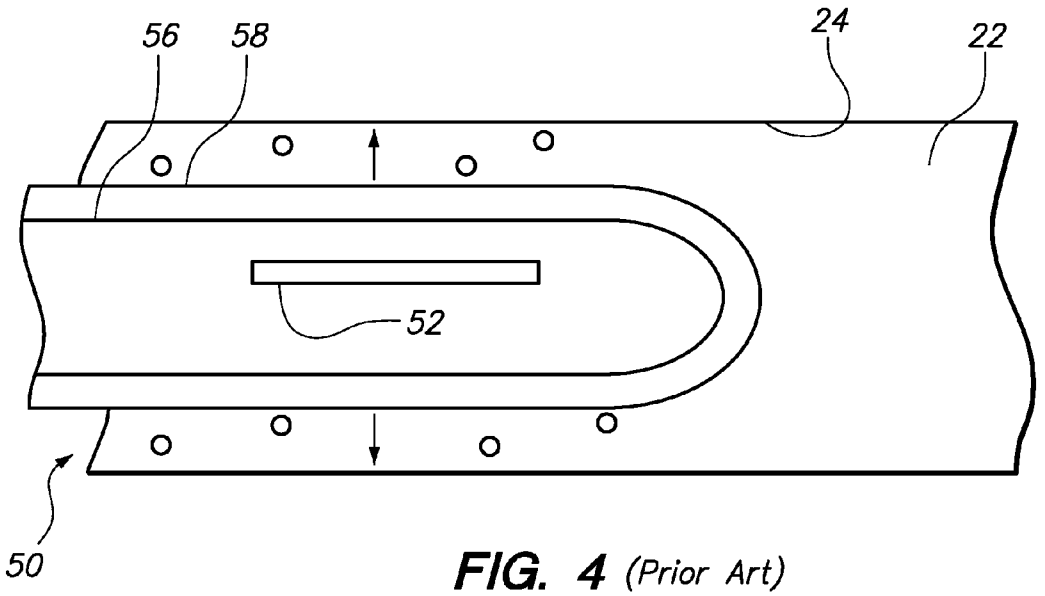


FIG. 4 (Prior Art)

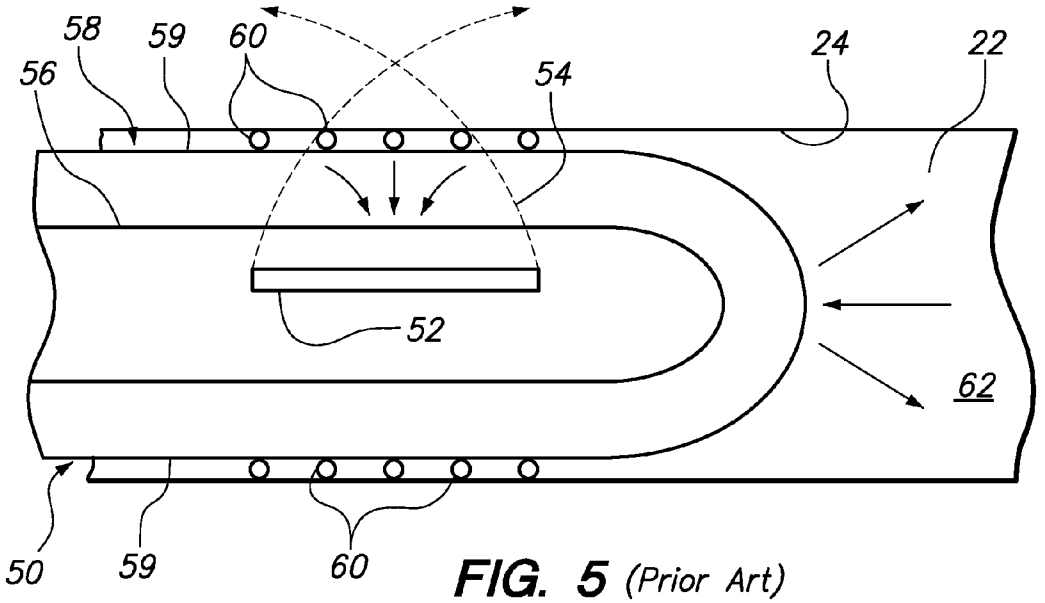


FIG. 5 (Prior Art)

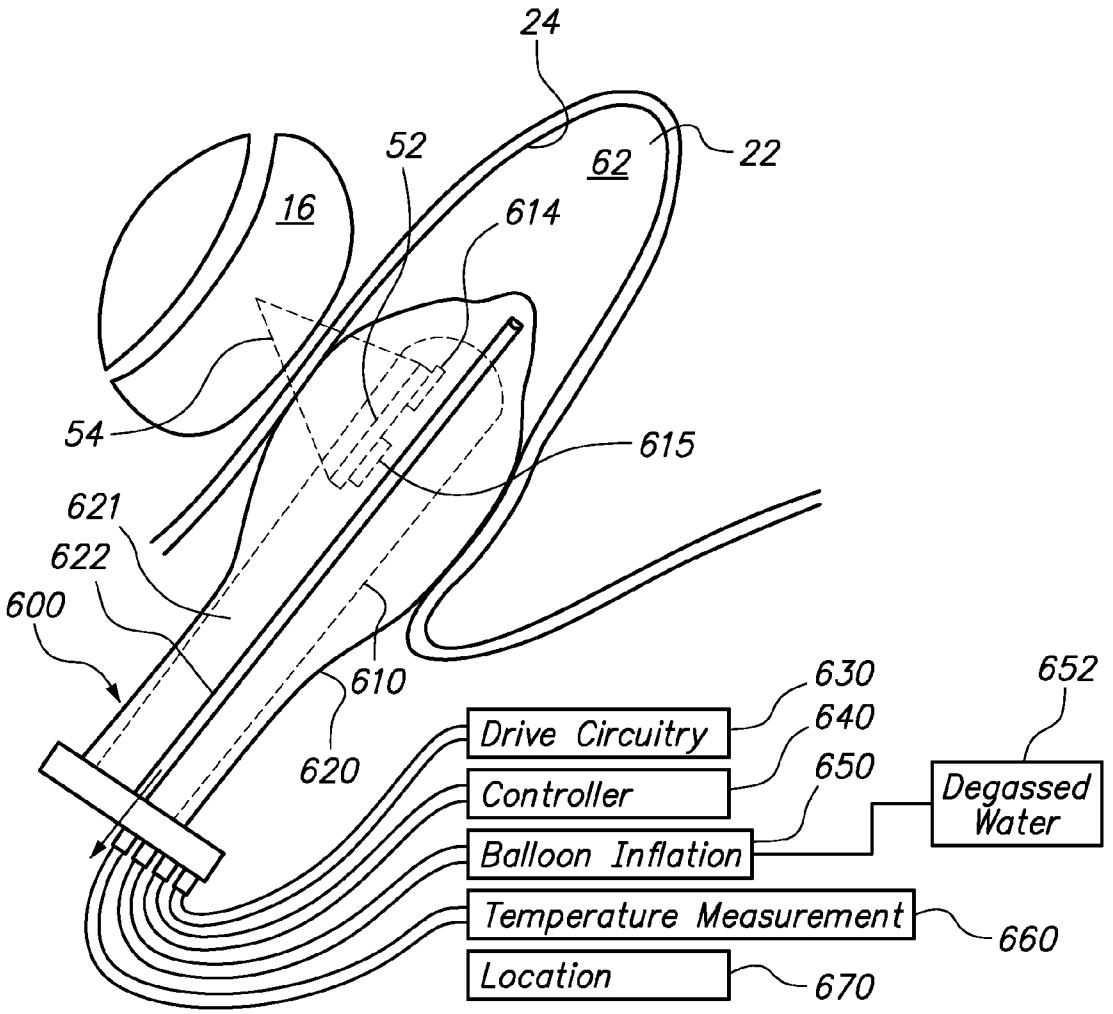

24
52
62
22
16
614
54
615
621
622
600
610
620
630
640
650
652
Drive Circuitry
Controller
Balloon Inflation
Degassed Water
Temperature Measurement
660
Location
670

FIG. 6

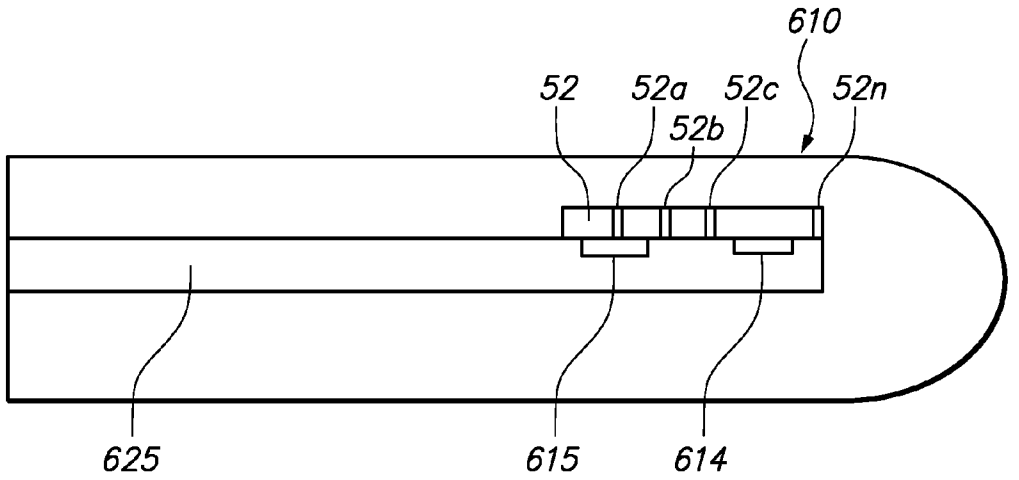

610
52
52a
52b
52c
52n
625
615
614

FIG. 7

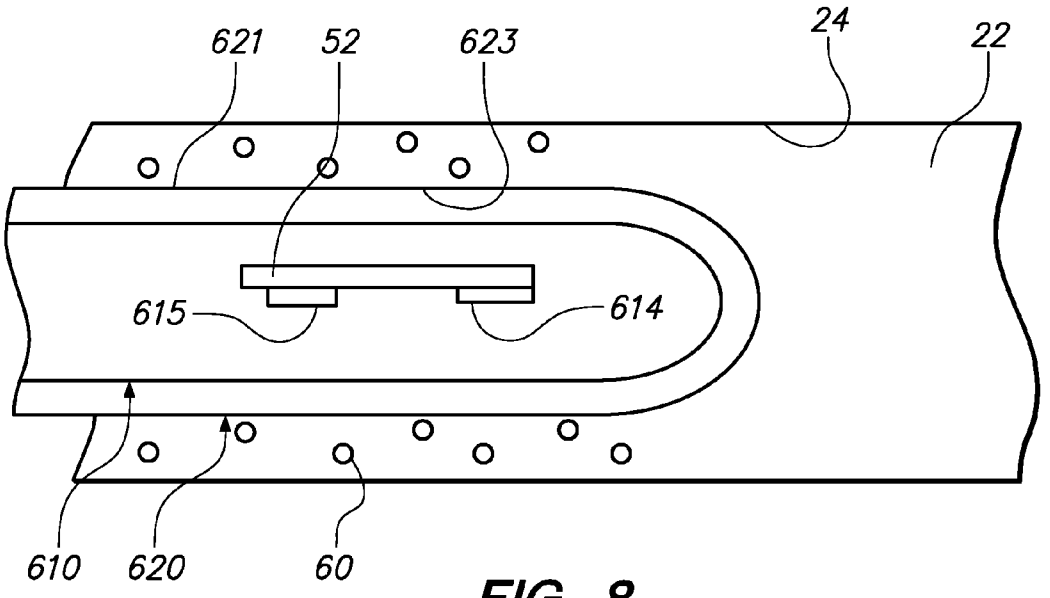

621
52
623
24
22
615
614
610
620
60

FIG. 8

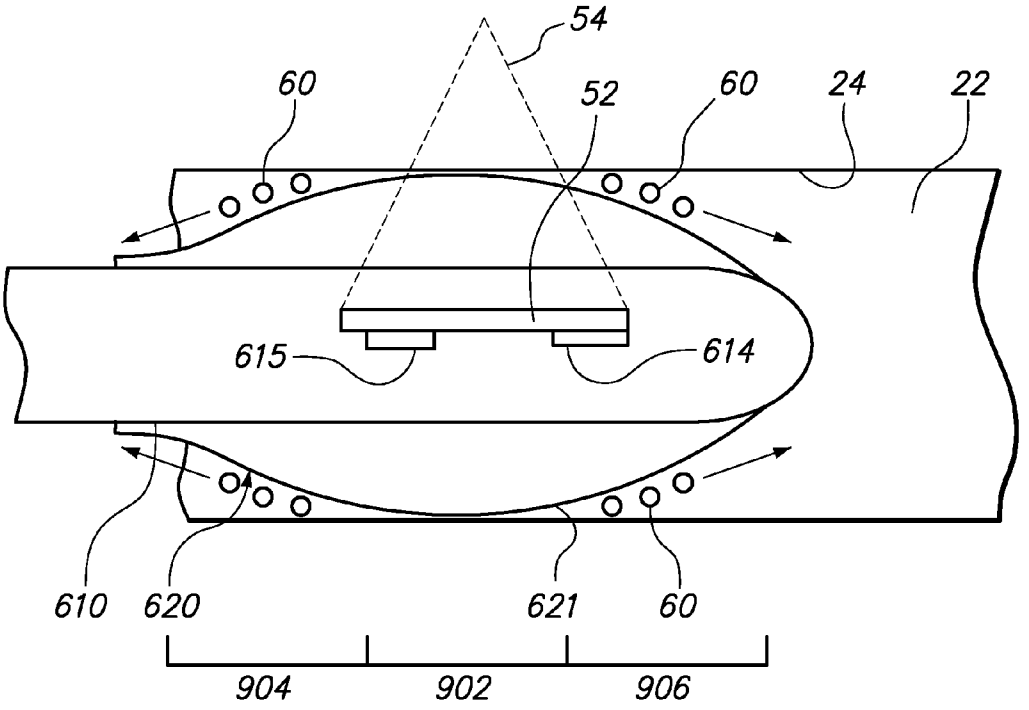

54
60
52
60
24
22
615
614
610
620
621
60
904
902
906

FIG. 9

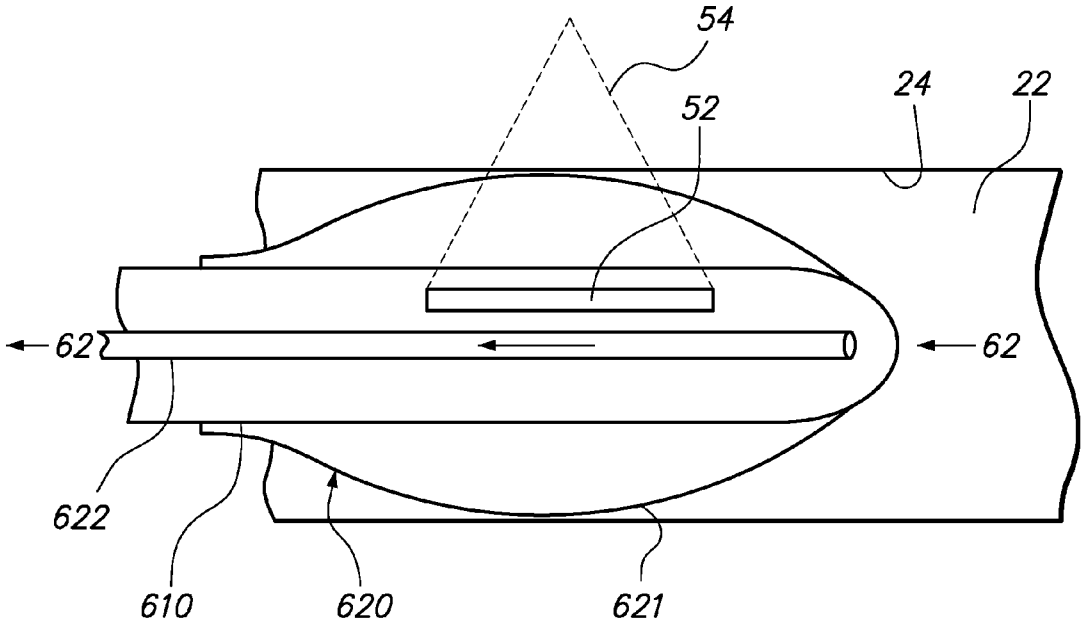

54
24
22
52
62
62
622
610
620
621

FIG. 10

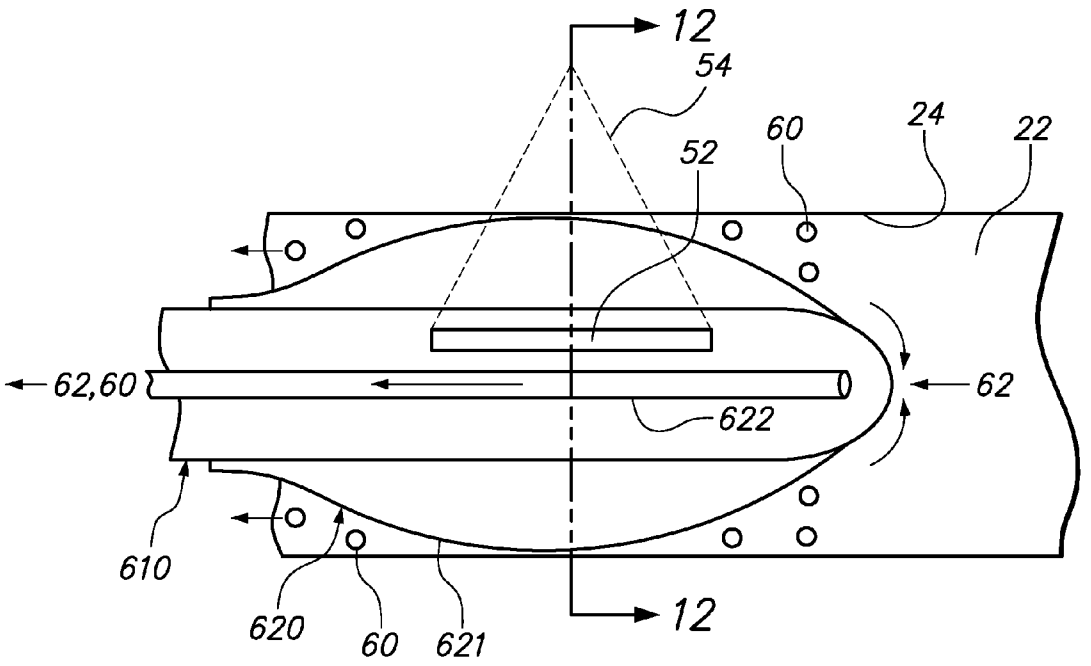

12
54
60
24
22
52
62,60
62
622
610
620
60
621
12

FIG. 11

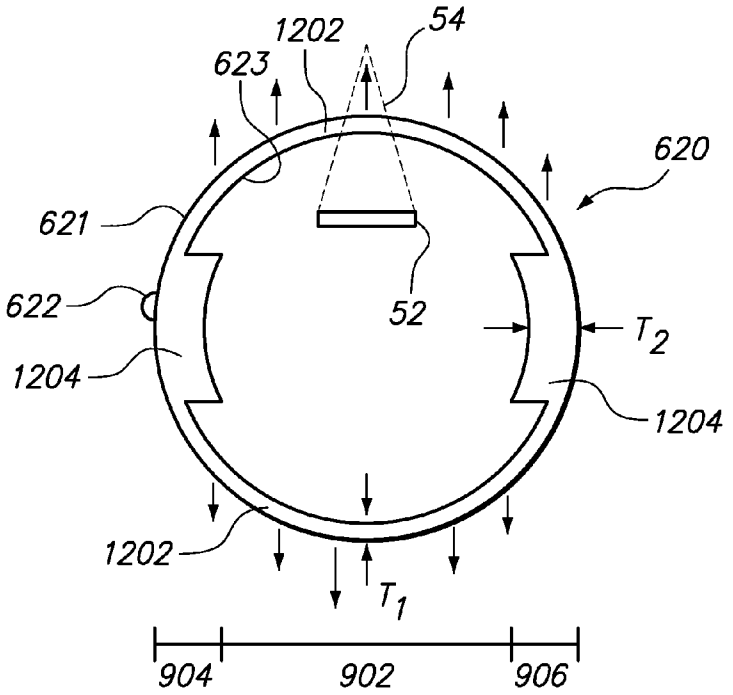

1202
54
623
620
621
622
52
T_2
1204
1204
1202
T_1
904
902
906

FIG. 12

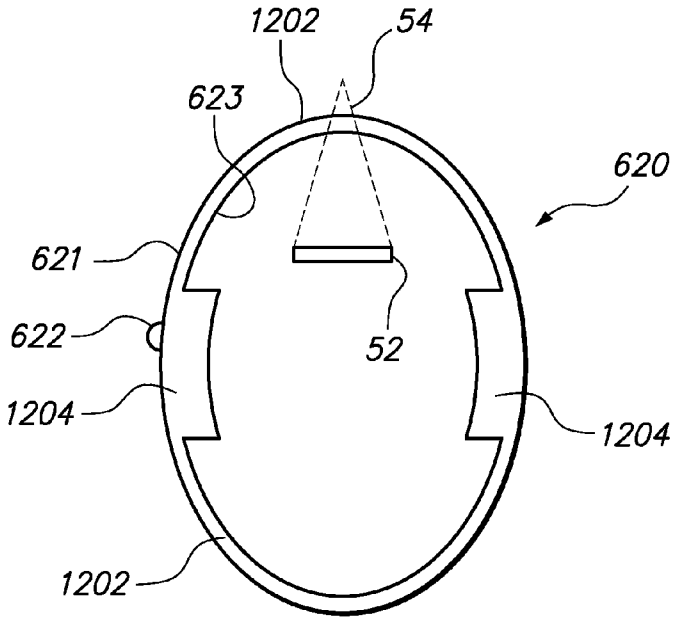

1202
54
623
620
621
622
52
1204
1204
1202

FIG. 13

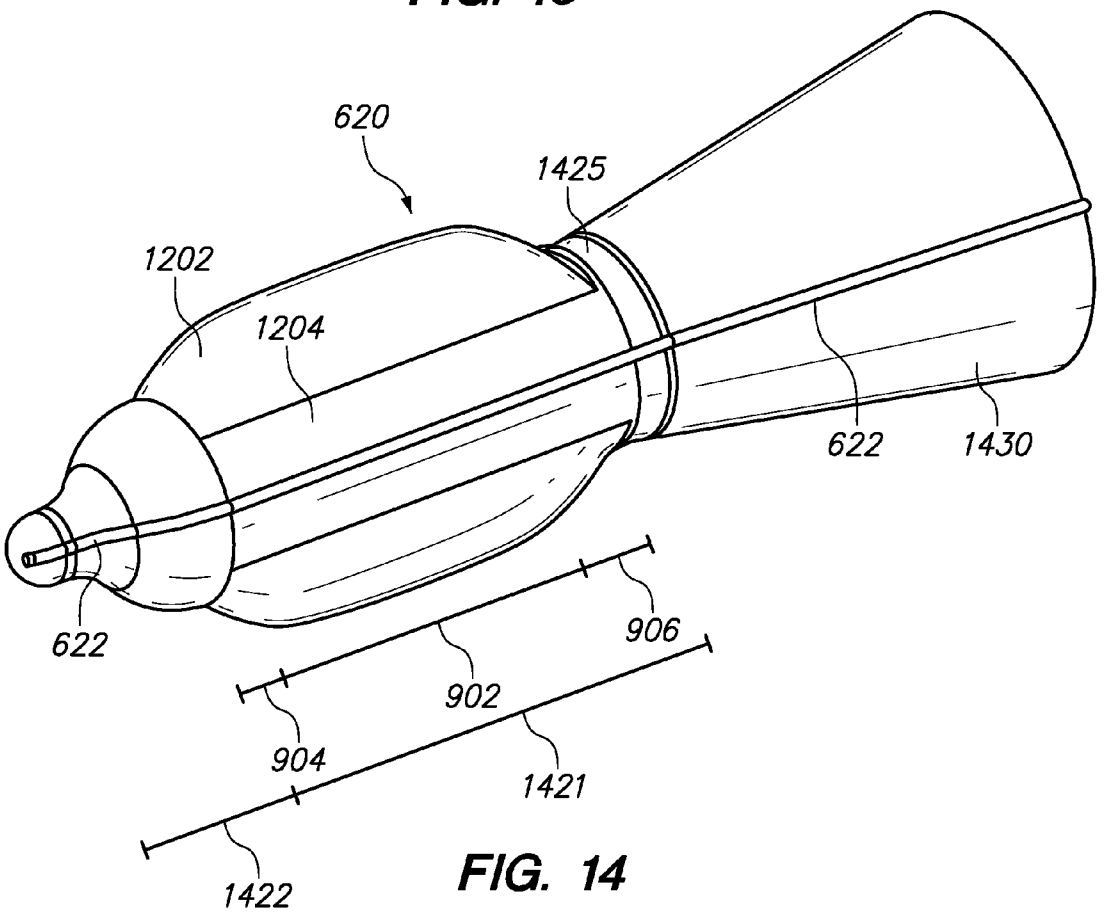

620
1425
1202
1204
622
1430
622
906
902
904
1421
1422

FIG. 14

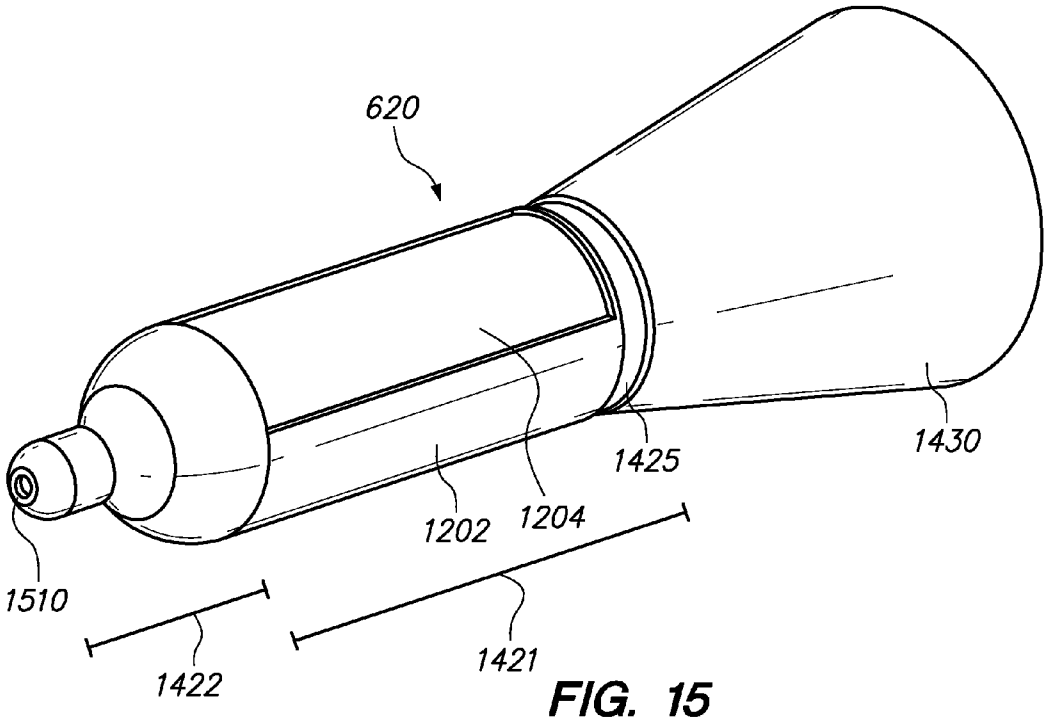

620
1425
1430
1202
1204
1510
1422
1421

FIG. 15

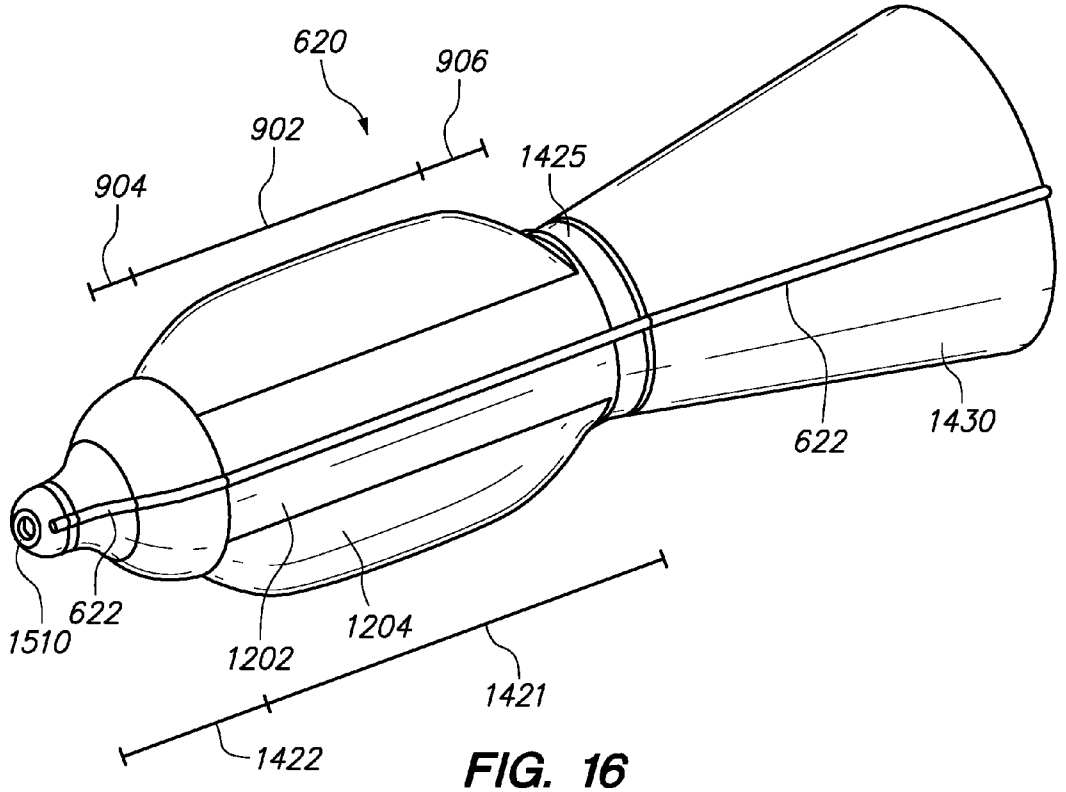

620
906
902
904
1425
622
1430
1510
622
1202
1204
1421
1422

FIG. 16

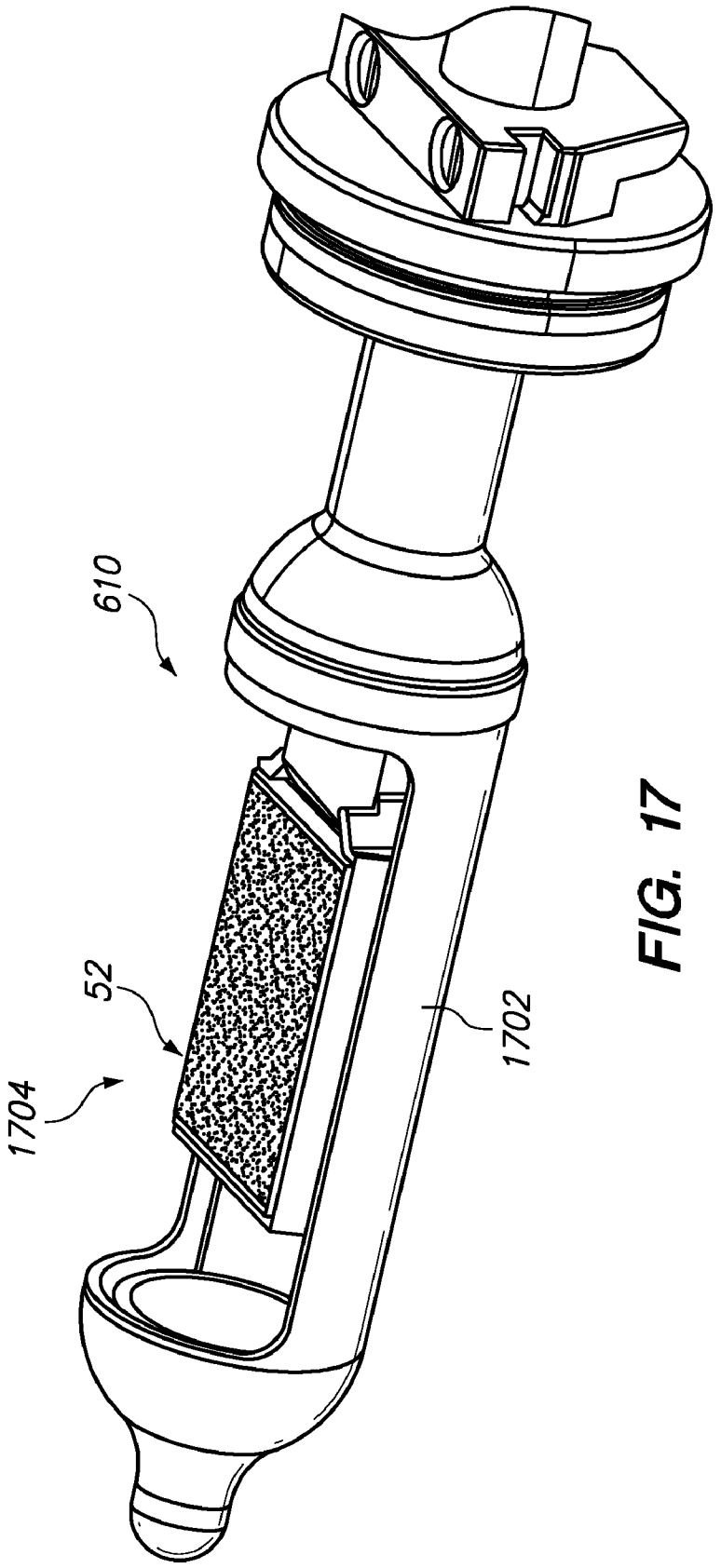


FIG. 17

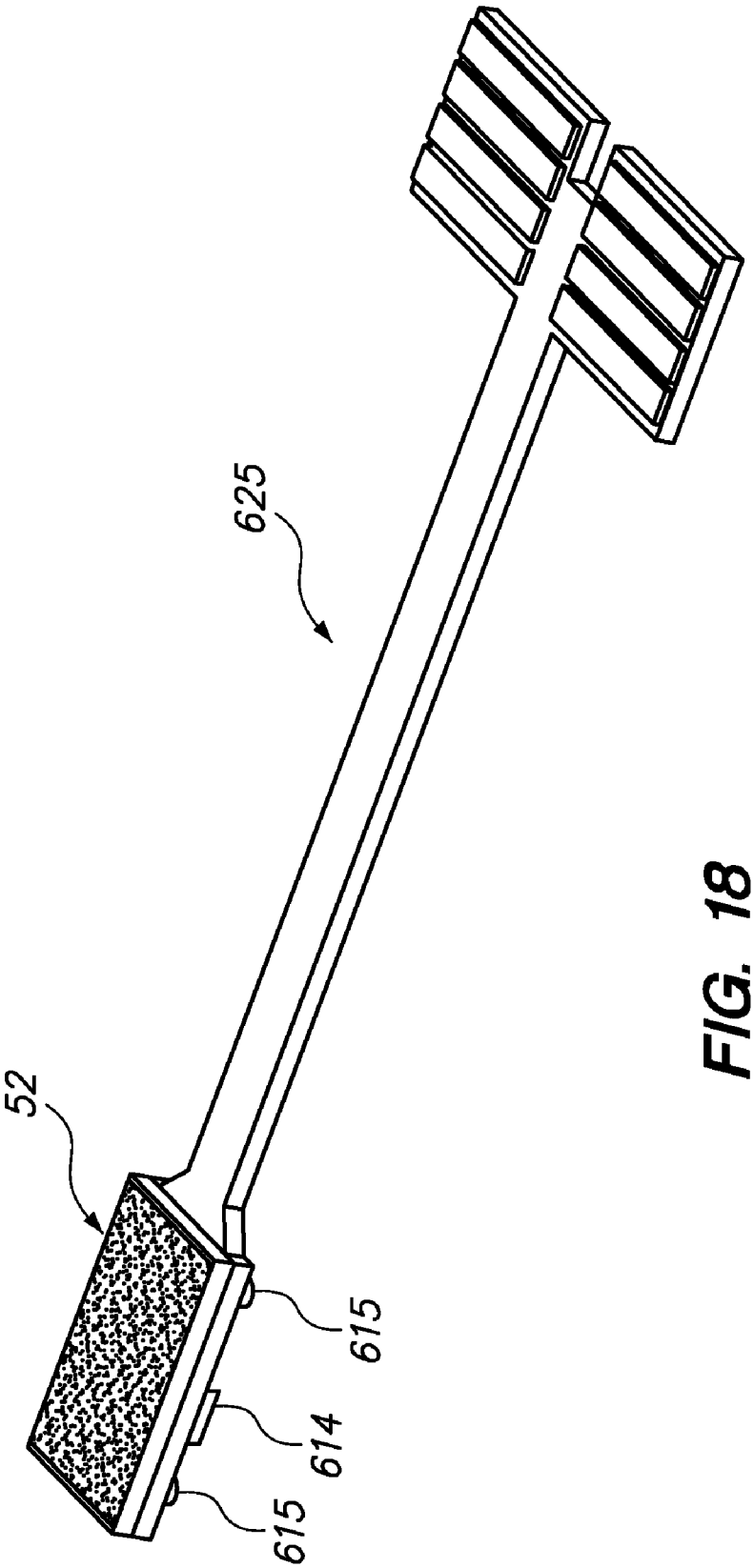


FIG. 18

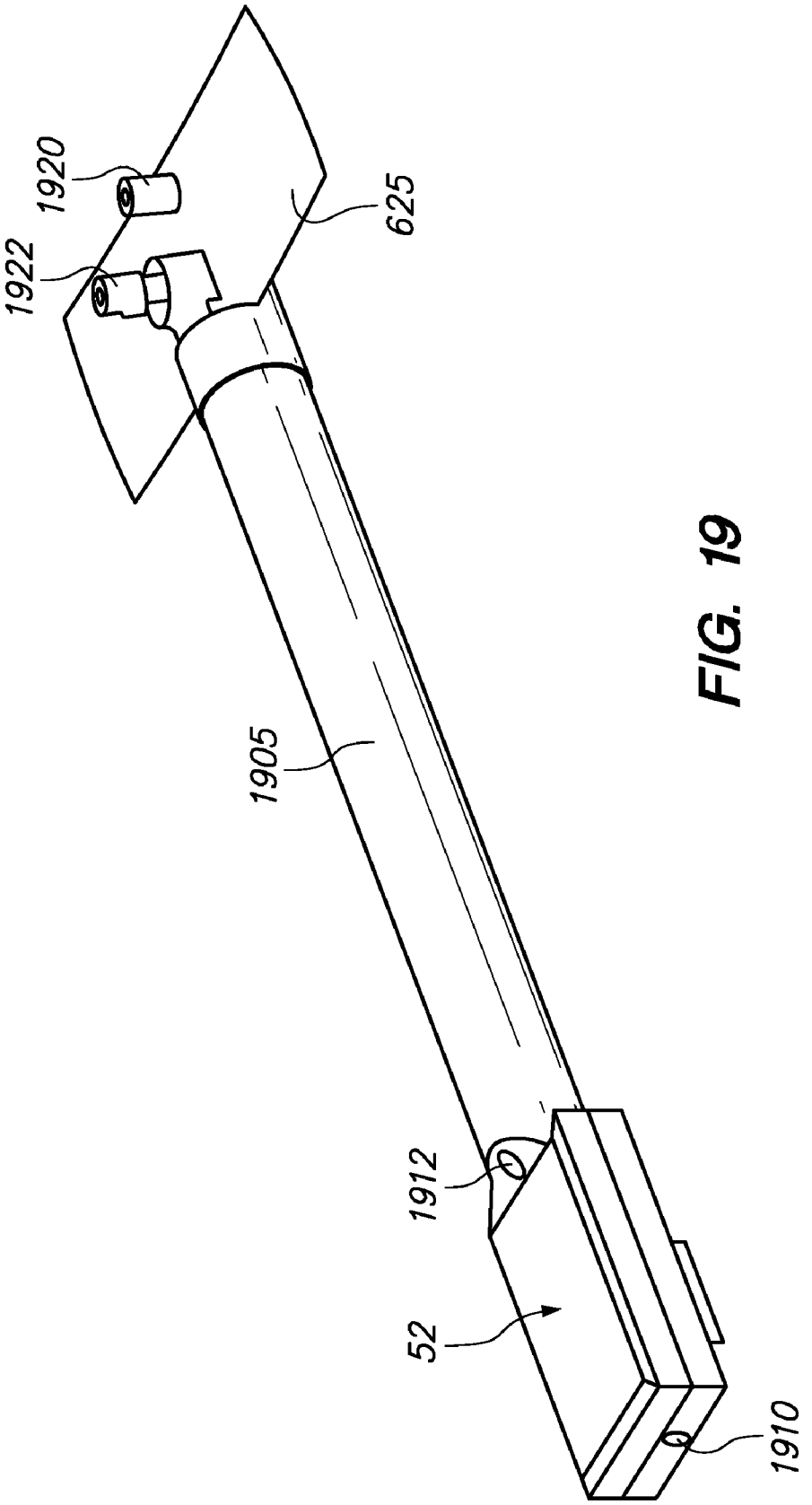


FIG. 19

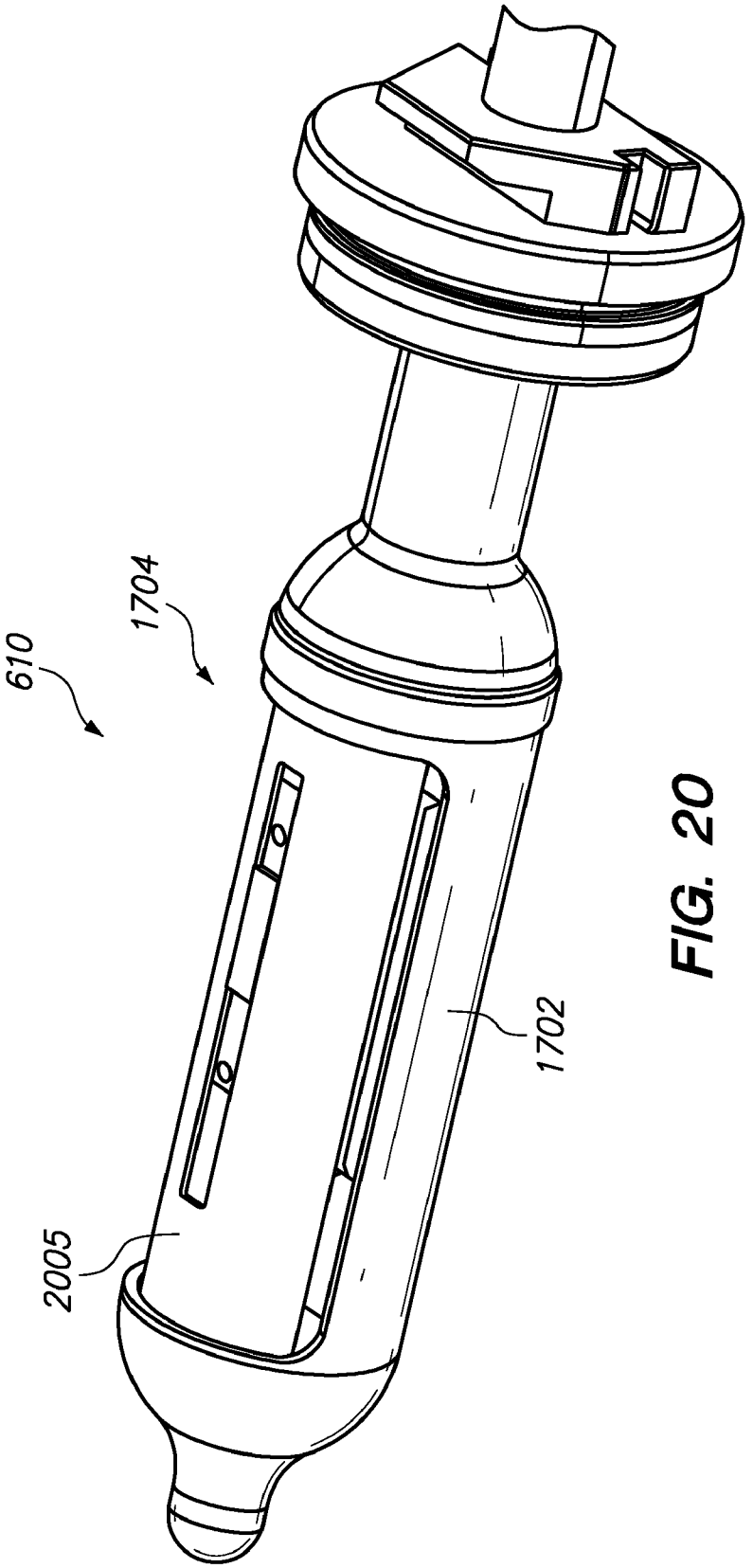


FIG. 20

TRANSRECTAL ULTRASOUND ABLATION PROBE

FIELD OF THE INVENTION

[0001] The field of the invention relates generally to rectal probes and, more particularly, to transrectal ultrasound ablation probes.

BACKGROUND

[0002] Various probe devices have been used for treatment of the prostate gland, for example, to treat prostate cancer and non-malignant prostatic hyperplasia (BPH). BPH is a well known condition that involves expansion of prostate tissue that may cause obstruction of the urethra. This may result in increased frequency of urination and slow or interrupted urinary streams and other complications.

[0003] FIG. **1** generally illustrates the anatomical structure of a male pelvic region and the location of the prostate **16** in relation to the urethra **10** and rectum **22**. The urethra **10** is a duct leading from a bladder **12**, out through an opening **14**, through the prostate **16**, and out an orifice **18** of the end of a penis **20**. Growth of the prostate **16** around the urethra **10** results in application of pressure or constriction around the urethra **10**, which can interrupt flow of urine from the bladder **12** and through the prostate **16**, which is adjacent to the rectum **22**.

[0004] Referring to FIG. **2**, a known system and method for treatment of the prostate **16** involves two probes—a transurethral ablation probe **30** and a transrectal temperature probe **40**. A known transurethral ablation probe **30** includes a catheter **32** that carries an ablation element **34**, such as a microwave antenna. The catheter **32** and microwave antenna **34** are inserted through the urethra **10** and positioned so that the microwave antenna **34** is adjacent the prostate **16**. A known transrectal temperature probe **40** in the form of a balloon **42** includes a temperature measurement or sensing device **44**. The temperature measurement device **44** is inserted into the rectum **22** and positioned so that the temperature sensing device **44** is in contact with the inner surface **24** of the rectum **22**.

[0005] Following positioning of the probes **30** and **40**, the microwave antenna **34** is energized and radiates microwave energy to heat and necrose adjacent prostate **16** tissue. For this purpose, the temperature of prostate **16** tissue is raised to a sufficiently high temperature, e.g., above about 45° C., for a sufficient time. The temperature measurement device **44** of the transrectal temperature probe **40** is held against the inner wall **24** of the rectum **22**, e.g., when the balloon **42** is inflated, to monitor the temperature of the rectum wall **24** during ablation of tissue by the transurethral ablation probe **30**. A cooling fluid can be delivered through the transrectal temperature probe **40** in order to cool the rectum **22** and avoid collateral tissue damage caused by ablation of prostate **16** tissue. In one known device, the temperature measurement device **44** is integrated within the expandable balloon **42**, i.e., within the body of the balloon **42** or the balloon **42** material itself. Thus, the temperature measurement device **44** can move with the balloon **42** as the balloon **42** expands and contracts. In these types of devices, the interior volume of the balloon **42** may be filled with cooling fluid. Examples of known transurethral ablation probes **30** and transrectal temperature probes **40** are described in U.S. Pat. Nos. 5,335,669; 6,009,351 and 6,348,039, the contents of which are incorporated herein by reference.

[0006] While known transurethral microwave ablation probes **30** and transrectal temperature probes **40** have been used effectively in the past, these devices and treatment techniques necessarily involve use of two separate probes. Multiple probes can complicate procedures and can increase patient discomfort. Additionally, use of microwave ablation elements may not be desirable since microwave energy may radiate from the antenna **34** in various or all directions, thus subjecting surrounding healthy tissue to microwave energy, resulting in collateral tissue damage.

[0007] Referring to FIG. **3**, it is also known to use a high intensity focused ultrasound (HIFU) probe **50** that includes an ultrasound transducer **52** that emits ultrasound or acoustic energy **54** for treatment of BPH and other prostate **16** conditions. One example of a known HIFU system is described in U.S. Pat. No. 5,676,692, the contents of which are incorporated herein by reference.

[0008] During use, the distal end of the ultrasound probe **50** is inserted into the rectum **22**, and the transducer **52** is activated to emit ultrasound energy **54**. It should be understood that a probe, such as probe **50**, is usually larger in diameter inside the rectum than the diameter at the anus. Thus, figures are provided for purposes of general illustration. The ultrasound energy **54** is focused at target prostate **16** tissue to heat and necrose selected portions of tissue. In this manner, HIFU ultrasound probes **50** provide targeted therapy by focusing energy **54**.

[0009] Referring to FIG. **4**, one known HIFU ablation probe **50** includes a probe body **56** that carries the transducer **52**. The probe body **56** is placed inside of a balloon **58**, and the assembly of the probe body **56** and balloon **58** is inserted into the rectum **22**. The balloon **58** is inflated or expanded outwardly (indicated by arrows) towards the inner wall **24** of the rectum **22**. An ultrasound gel (not shown) may be applied around the balloon **58** to provide desired acoustic coupling between the probe and the inner wall **24**. The balloon **58** is filled with water that is circulated, chilled and degassed to protect the inner wall **24** from heat damage and for acoustic coupling.

[0010] The transducer **52** is activated and the resulting focused acoustic energy **54** heats and necroses prostate tissue. Thus, with a HIFU probe, ablation energy **54** can be delivered from the rectum **22** to target prostate tissue rather than from the urethra **10** to target prostate tissue. Further, acoustic energy can be focused and emitted in a particular direction and location rather than emitted in multiple directions as the case with microwave antennas **34**.

[0011] While known transrectal HIFU probes **50** have been used effectively in the past and provide certain advantages over microwave-based systems, they can be improved. For example, referring to FIG. **5**, use of known transrectal HIFU probes **50** may result in trapping of air bubbles **60** between the outer surface **59** of the balloon **58** and the inner wall **24** of the rectum **22**. This may be caused by the isotropic elasticity or expansion of the balloon **58** (as shown in FIG. **5**) used in known probes **50**.

[0012] Trapped air bubbles **60** can cause a number of problems during treatment. For example, bubbles **60** may interfere with or block acoustic energy **54** emitted by the transducer **52**. Consequently, all of the required acoustic energy **54** may not be applied to the prostate **16**, thereby reducing the effective-

ness of the procedure, possibly resulting in longer or multiple procedures, or having to reposition or reconfigure the probe **50** in an attempt to eliminate or displace trapped bubbles **60**. Trapped air bubbles **60** may also cause acoustic energy **54** to reflect back on the transducer **52**. This may result in acoustic energy **54** that adversely affects the rectum **22**. Ultrasound gel that is often applied around the balloon **58** may present additional complications since air bubbles **60** are readily trapped within the gel. Additionally, air bubbles can be difficult to remove due to limited access and difficulties in identifying the air bubbles **60**. Thus, bubbles **60** in the interface between the balloon **56** and the inner wall **24** of the rectum **22** can limit or inhibit effective use of HIFU ultrasound probes **50**.

[0013] During a procedure, it is also desirable to prevent movement of the prostate **16**, e.g., caused by discharge of bowel gas **62** through the rectum **22**. However, when the balloon **58** is inflated, the balloon may seal the rectum **22**, thereby blocking bowel gas **62** from passing through rectum **22**, as generally illustrated in FIG. **5**. The resulting accumulation of gas **62** inside the rectum **22** can cause the prostate **16** to move. Pressure from accumulated gas **62** may also cause patient discomfort, causing the patient to move or shift in order to alleviate the discomfort, thereby resulting in movement of the prostate **16**.

[0014] Thus, it is desirable to have a transrectal ultrasound ablation probe that can eliminate or reduce air bubbles that would otherwise be trapped between an outer surface of a known balloon and an inner rectal wall in order to provide a more consistent interface, improve acoustic coupling and reduce other adverse effects. It is also desirable to vent bowel gas from within the rectum to the body exterior in order to reduce bowel gas buildup and reduce prostate movement and patient discomfort.

SUMMARY

[0015] According to one embodiment, a transrectal ultrasound probe includes a probe body carrying an ultrasound transducer, an anisotropic balloon member, and a tube. The anisotropic balloon member defines a cavity configured for receiving the probe body, and the tube is associated with an outer surface of the anisotropic balloon member. The tube is configured for venting of rectal gas.

[0016] According to another embodiment, a transrectal ultrasound probe includes a probe carrying an ultrasound transducer for treating or ablating tissue, a balloon member, a tube, and a temperature sensor. The balloon member defines a cavity configured for receiving the probe body. A thickness of a middle portion of the balloon member is less than a thickness of balloon member portions adjacent the middle portion. The tube is conformable with an outer surface of the balloon member and may be used to vent rectal gas. The temperature sensor is associated with the ultrasound transducer.

[0017] Another embodiment is directed to a method of ablating tissue of a patient that includes inserting a probe into a rectum of the patient. The probe has a probe body carrying an ultrasound transducer, a balloon member defining a cavity configured for receiving the probe body, and a tube conformable with an outer surface of the balloon member. The method further includes activating the ultrasound transducer and ablating tissue using ultrasound energy emitted by the ultrasound transducer. The method may further include venting rectal gas through the tube and outside of the patient. The method may also include venting air from within the balloon member through a duct defined by a distal end of the balloon member.

[0018] In one or more embodiments, the transducer is a focused ultrasound transducer that includes an array of ultrasound transducer elements. The probe body may define a window for the ultrasound transducer, and cover element may be rotatably positionable within the probe body to expose and cover the ultrasound transducer.

[0019] In one or more embodiments, different portions of the anisotropic balloon member having different thicknesses. For example, a thickness of middle portion of the anisotropic balloon member may be less than a thickness of portions of the anisotropic balloon member adjacent the middle portion, and the middle portion may expand more than the adjacent portions when the anisotropic balloon member is inflated.

[0020] In one or more embodiments, the tube is attached to the outer surface of the anisotropic balloon member and is conformable to a shape (e.g., non-linear shape) of the anisotropic balloon member. Embodiments may be configured so that no portion of the tube is positioned inside the anisotropic balloon member. A distal end of the anisotropic balloon member may also define a duct for venting air from within the anisotropic balloon member.

[0021] In one or more embodiments, a probe may include a temperature sensor associated with the ultrasound transducer, but which is not attached to the anisotropic balloon member. Further, a probe may include location sensor that may include magnetic resonance micro-coils.

[0022] Other aspects and features of the embodiments will be evident from reading the following description of the embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] Referring now to the drawings in which like reference numbers represent corresponding parts throughout and in which:

[0024] FIG. **1** is a sectional view of a male patient's pelvic region;

[0025] FIG. **2** generally illustrates a known multi-probe system for treating the prostate including a transurethral ablation probe and a transrectal temperature probe;

[0026] FIG. **3** generally illustrates a known system for treating the prostate and that includes a transrectal ultrasound ablation probe;

[0027] FIG. **4** further illustrates a known transrectal ultrasound ablation probe within an isotropic balloon;

[0028] FIG. **5** illustrates isotropic expansion of the balloon shown in FIG. **4** and resulting trapping of air bubbles between the outer surface of the isotropic balloon and the inner surface of the rectum to seal;

[0029] FIG. **6** illustrates a focused ultrasound ablation probe and system according to one embodiment that includes a probe body positioned within an inflated anisotropic balloon;

[0030] FIG. **7** further illustrates a probe body for use with embodiments;

[0031] FIG. **8** illustrates a probe body within a deflated or partially inflated anisotropic balloon inserted within a rectum according to one embodiment;

[0032] FIG. **9** shows how inflation of the anisotropic balloon displaces air bubbles from the center of the anisotropic balloon and sideways away from the center of the balloon according to one embodiment;

[0033] FIG. **10** shows how the ultrasound ablation probe shown in FIG. **9** can also be used for venting of bowel gas according to one embodiment;

[0034] FIG. **11** further illustrates how the ultrasound ablation probe shown in FIGS. **8** and **9** can be used for venting of bowel gas and venting of air from air bubbles displaced by the anisotropic balloon according to another embodiment;

[0035] FIG. **12** is a cross-sectional view of a deflated or partially inflated balloon illustrating different balloon portions configured for anisotropic expansion when inflated;

[0036] FIG. **13** illustrates the anisotropic balloon illustrated in FIG. **12** when inflated;

[0037] FIG. **14** illustrates another embodiment of an anisotropic balloon including hygienic shield and a vent line associated with an outer surface of the balloon and extending along a length of the balloon;

[0038] FIG. **15** illustrates another embodiment of an anisotropic balloon including an air release port at a distal tip of the balloon for bleeding or releasing air from the interior of the balloon;

[0039] FIG. **16** illustrates another embodiment of an anisotropic balloon including an external gas venting tube and an air release port at a distal tip of the balloon;

[0040] FIG. **17** illustrates a probe shell or housing of a probe body that carries an ultrasound transducer for use with embodiments;

[0041] FIG. **18** illustrates a circuit board or substrate for carrying an ultrasound transducer for use with embodiments;

[0042] FIG. **19** illustrates a shaft for carrying the probe shell and circuit board shown in FIGS. **17** and **18**; and

[0043] FIG. **20** illustrates a probe body including a rotatable shield for covering an ultrasound transducer positioned inside a probe shell or housing.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0044] Embodiments are directed to transrectal ultrasound or HIFU ablation probes, ablation systems and methods for improving acoustic coupling by eliminating or reducing air bubbles between an outer surface of a balloon and an inner wall of a rectum while venting bowel gas from within the rectum during treatment. Embodiments achieve these advantages by use of an anisotropic balloon or condom that is placed over a distal end of an ultrasound probe body or housing, and an external vent tube or duct associated with an outer surface of the anisotropic balloon.

[0045] Referring to FIGS. **6** and **7**, a transrectal ultrasound probe **600** according to one embodiment includes a probe body **610** (illustrated in phantom in FIG. **6**) and an anisotropic balloon or condom member **620** (generally referred to as anisotropic balloon **620**) that is applied over a distal end of the probe body **610**. The probe body **610** carries an ultrasound transducer **52** (illustrated in phantom in FIG. **6**) and associated electrical components, such as a circuit board **625** to which the transducer **52** is mounted for controlling and driving the transducer **52**. The transducer **52** may be an array of multiple ultrasound transducer elements (**52***a-n*), which may be individually controllable in order to achieve proper focusing of acoustic energy **54**.

[0046] A temperature measurement device or sensor **614** and one or more location sensors **615** are associated with, e.g., coupled to, the transducer **52** or the circuit board **625**. In the illustrated embodiment, the temperature sensor **614** and the location sensor **615** are coupled to an underside of the circuit board **625**, but other configurations may be utilized as necessary. Further, in the illustrated embodiment, the temperature and location sensors **614**, **615** are inside of the probe body **610**, and are not associated with, attached to, or part of the anisotropic balloon **620** or balloon **620** material.

[0047] The temperature sensor **614** is used to monitor the temperature of the transducer **52** to ensure that the temperature of the transducer **52** does not exceed a threshold temperature. The temperature sensor **614** may also be used to monitor ambient temperature to verify the cooling effect of water inside the probe body **610** and anisotropic balloon **620** and that circulates around the transducer **52**.

[0048] The location sensor **615** may also be used in order to accurately track the position of the transducer **52**. According to one embodiment, the location sensor **615** may include one or more micro magnetic resonance imaging (MRI) coils that are used to localize the transducer **52** in the MRI image space. According to one embodiment, multiple micro-coils, e.g., four micro-coils, may be mounted on the underside of the circuit board **625**. The probe **600** may include non-magnetic materials that are compatible with magnetic resonance imaging in order to reduce or minimize imaging artifacts.

[0049] The transrectal ultrasound probe **600** can be driven and controlled using ultrasound ablation system components including suitable drive circuitry **630**, which provides electrical drive signals to the transducer **52** through the circuit board **625** or other suitable substrates or connectors. A controller **640** controls drive signals that are provided by the drive circuitry **630**. The anisotropic balloon **620** can be inflated by balloon inflation element **650** that utilizes a source of degassed water **652** or other suitable fluid or material suitable for acoustic coupling. A temperature measurement element **660** can determine or output the temperature sensor **614** within the probe body **610**, and a location device or system **670** can be used to monitor the position of the transducer **52** using the location sensor **615**. Circuit board **625**, drive circuitry **630**, controller **640**, balloon inflation **650**, temperature measurement **660** and location or MR **670** devices are well known and, therefore, are not described in further detail.

[0050] In embodiments, the balloon **620** is anisotropic in that the elasticity and/or expansion of the balloon **620** varies along the length of the balloon **620**. More particularly, in embodiments, an "anisotropic" balloon **620** has certain sections or portions that expand or inflate whereas other sections or portions do not, certain sections or portions that expand at different rates, and/or certain sections or portions that expand to different degrees or diameters. For example, in the embodiment illustrated in FIG. **6**, when the anisotropic balloon **620** is inflated, a middle portion of the balloon **620** expands before adjacent end portions of the balloon **620**, and/or to a larger diameter or dimension compared to adjacent end portions of the balloon **620**, which may or may not be expandable.

[0051] A vent duct or vent tube **622** (generally vent tube **622**) is associated with an outer surface **621** of the anisotropic balloon **620** to allow venting of bowel gas **62** in the rectum **22**. Venting of bowel gas **62** prevents accumulation of gas **62** inside the rectum **22** in order to enhance patient comfort and reduce pressure on the prostate **16**, thereby reducing or eliminating movement of the prostate **16** due to bowel gas **62**. Although this specification refers to a "tube," it should be understood that a "tube" can have various shapes, including circular shapes. Further, a "tube" can be a conduit, aperture, or other cavity through which a gas or fluid, such as bowel gas

62, can pass when the ultrasound ablation probe **600** is positioned inside the rectum **22** of a patient.

[0052] In one embodiment, the vent tube **622** is attached (e.g., adhered) to the outer surface **621** of the anisotropic balloon **620**. In another embodiment, the vent tube **622** is integral with the outer surface **621** of the balloon **620**. In one embodiment, the vent tube **622** is embedded within or formed with the material forming the anisotropic balloon **620** and extends along the length of the balloon **620** to allow venting of gas **62**. For example, the vent tube **622** can be molded within or to be a part of the balloon **620** material. Thus, the proximal and distal ends of the vent tube **622** are exposed to allow venting of gas, whereas middle portions of the vent tube **622** may or may not be visible depending on the manner in which the vent tube **622** is associated with the outer surface **621** of the balloon **620**.

[0053] The vent tube **622** is preferably flexible and conformable to the shape of the outer surface **621** of the anisotropic balloon **620** so that the vent tube **622** can bend with or assume the shape of a curved outer surface **621** of the balloon **620**. Further, the vent tube **622** can conform or bend as the anisotropic balloon **620** is inflated and deflated. The flexibility of the balloon **620** and vent tube **622** also facilitates insertion of the probe into the rectum **22**. Although FIG. **6** illustrates a vent tube **622** extending along a length of the anisotropic balloon **612**, the vent tube **622** may be shorter or longer while still being capable of venting gas **62**. For example, the vent tube **622** may extend from the distal end of the balloon **620** and be sufficiently long so that it extends outside of the patient and beyond the anus.

[0054] Following is a more detailed description of components of probe embodiments and how embodiments may be used for treatment of the prostrate **16** with reference to FIGS. **8-20**. FIGS. **8-13** further illustrate how embodiments that use an anisotropic balloon **620** provide advantages over known ultrasound probes that use isotropic balloons, and one manner in which the anisotropic balloon **620** may be made. FIGS. **14-16** further illustrate embodiments of a balloon **620** having vent tubes **612** associated with an outer surface **621** of the anisotropic balloon **620** may be used to vent gas **62** from the rectum **22** and having a release vent or valve for bleeding air from within the anisotropic balloon **620**. FIGS. **17-20** are renderings a probe body **610** and components thereof for use in various embodiments.

[0055] Prior to insertion, the anisotropic balloon **620** is placed over a distal end of the probe body **610**. The anisotropic balloon **620** may initially be filled with a small amount of water to displace the area inside the anisotropic balloon **620** between the transducer **52** and the inner surface **623** of the balloon **620** to verify that the balloon **620** is free of leaks.

[0056] Referring to FIG. **8**, the anisotropic balloon **620**/probe body **610** assembly may be inserted into the patient through the rectum **22**. An ultrasound gel may be applied around the outer surface **621** of the anisotropic balloon **620** to facilitate insertion of the probe **600** into the patient and to provide desired acoustic coupling. FIG. **8** illustrates the anisotropic balloon **620** in a partially or completely deflated state (e.g., when using a small amount of water to test for leaks) and positioned inside the rectum **22**. Air bubbles **60** may exist between the outer surface **621** of the deflated balloon **620** and the inner surface **24** of the rectum **22** (e.g., within the ultrasound gel).

[0057] It should be understood that FIG. **8** is provided to generally illustrate the presence of air bubbles **60** in the space between the anisotropic balloon **620** an the inner surface **24** of the rectum **22**, and that the dimensions illustrated in FIG. **8** may not accurately reflect actual dimensions. For example, the transrectal ultrasound probe **600** may be configured so that the outer surface **621** of the anisotropic balloon **620** contacts the inner surface **24** of rectum **22**, but air bubbles **60** may nevertheless exist between the balloon's outer surface **621** and the rectal inner surface **24**.

[0058] Referring to FIG. **9**, after the anisotropic balloon **620** is properly positioned inside the rectum **22**, the balloon **620** is inflated using, e.g., degassed water **652**, or another suitable fluid or material, to a fully expanded or inflated state. In the illustrated embodiment, a middle portion **902** of the anisotropic balloon **620** initially expands, followed by expansion of proximal and distal portions **904** and **906** on each side of the middle portion **902**. In an alternative embodiment, the middle portion **902** expands to a greater degree or at a faster rate relative to proximal and distal portions **904** and **906**. In certain embodiments, the middle portion **902** may expand, and the proximal and distal portions **904** and **906** may be fixed and not expand at all.

[0059] Thus, during inflation, the anisotropic design and elasticity of the balloon **620** advantageously allows the balloon **620** to expand from the center and outwardly or sideways from the center towards the other portions or ends **904** and **906** of the balloon **620**. As a result, the outer surface **621** of the balloon **620** pushes air bubbles **60** sideways and away from the center of the balloon **620** along the inner surface **24** of the rectum **22**. This allows bubbles **60** to escape or be pushed away from the outer surface **621** that contacts the inner rectal wall **24**, thereby forming a bubble-free or substantially bubble-free interface between the outer surface **621** of the balloon **620** and the inner surface **24** of the rectum **22**.

[0060] It should be understood that the length of the middle portion **902** can vary, and that during inflation, different portions of the outer surface **621** of the balloon **620** may contact the inner surface **24** of the rectum **22** while pushing the air bubbles **60** away. The balloon **620** may expand sideways from the center of the balloon and outwardly in proximal and distal directions so that only the middle portion **902** engages the inner surface **24**, or two or more or all of the portions **902**, **904** and **906** engage the inner surface **24** and form a bubble-free or substantially bubble-free interface.

[0061] The resulting bubble-free or substantially bubble-free interface improves acoustic coupling and reduces or eliminates interference and reflections of acoustic energy **54** reflections that may otherwise result from trapped air bubbles **60** resulting from use of a known isotropic balloon (as illustrated in FIG. **5**). Thus, acoustic energy **54** from the transducer **52** can be properly focused and applied to target prostate **16** tissue with greater accuracy compared to known ultrasound probes that use an isotropic balloon.

[0062] Referring to FIG. **10**, a semi-rigid duct or tube **622** associated with, e.g., attached or integrated within, the anisotropic balloon **620** vents gas **62** inside the rectum **22**, through the tube **622**, and outside of the body. In the illustrated embodiment, the distal end of the vent tube **622** is adjacent the distal tip of the anisotropic balloon **620**, however, the vent tube **622** may extend to different lengths while being capable of venting gas **62**. Referring to FIG. **11**, in addition to venting gas **62**, air from displaced air bubbles **60** may also be vented through the tube **622**. Further, a portion of the tube **622** located outside of the body can include a standard syringe interface to allow pumping of air into the rectum **22** or with-

drawing of fluid from the tube **622** in the event of an obstruction within the tube **622**. Additionally, although FIGS. **10** and **11** illustrate a single vent tube **622**, alternative embodiments may include multiple vent tubes **622** associated with an outer surface **612** of the anisotropic balloon **620**.

[0063] FIG. **12** is a cross-sectional view of an anisotropic balloon **620** according to one embodiment that is a multi-element or multi-section balloon having portions of different thicknesses in order to control or restrict the extent of and/or direction of expansion (illustrated by arrows) and the resulting shape of the inflated balloon **620**. In one embodiment, portions **1202** of the balloon **620** are thinner than portions **1204** and expand when inflated (as shown in FIG. **13**), whereas portions **1204** are rigid or semi-rigid and do not expand, or expand to a lesser degree. The ends of the portions **1202** are coupled to probe components such that air bubbles **60** are displaced from the center of the balloon **620** by the portions **1202** when the balloon is inflated (as shown in FIGS. **13** and **14**). Further, since the vent tube **622** is associated with the rigid or semi-rigid portion **1204** of the balloon **620**, gas venting can be achieved through the external vent tube **622** without obstructing the path of an acoustic beam **54** emitted by an transducer **52** through an expandable or flexible portion **1202** of the anisotropic balloon **610**. FIGS. **12** and **13** illustrate an embodiment in which different portions **1202** and **1204** of the balloon **620** have different discrete thicknesses. In alternative embodiments, the thickness of different portions **1202** and **1204** can vary gradually. Accordingly, FIGS. **12** and **13** are provided to illustrate one manner in which embodiments can be implemented.

[0064] FIG. **14** illustrates one embodiment of an anisotropic balloon member **1420** that includes an inflatable portion **1421** and a non-inflatable rounded distal portion **1422**. The inflatable portion **1421** includes portions **1202** and **1204**, e.g., an inflatable portion **1202** and a non-inflatable, rigid or semi-rigid portion **1204** to provide anisotropic expansion. A coupling or sealing ring **1425** is provided at a proximal end of the balloon **620** for sealing the interior volume of the balloon **610** to prevent leakage of water from inside the balloon **620** to the environment. Further, the balloon **620** is rigidly attached to a portion of the probe body **610** in order to prevent the balloon **610** from inflating into the rectal cavity. The rigid or semi-rigid portions **1204** also restrict the direction of expansion and shape of the inflated balloon **620**.

[0065] A hygienic annular member **1430** may be attached to a base or proximal end of the anisotropic balloon **620**, e.g., adjacent to the coupling ring **1425**, to provide a protective barrier between a physician and the patient. In the illustrated embodiment that includes the optional annular member **1430**, the vent tube **622** extends along the annular member **1430**, across the coupling ring **1425**, and along the portions **1421** and **1422**. In the illustrated embodiment, the vent tube **622** is associated with the rigid or semi-rigid portion **1204** of the balloon **620**. In the illustrated embodiment, the portion **1204** is a portion of the anisotropic balloon **620** that is not expandable, whereas portion **1202** (e.g., which can be thinner than portion **1204**) is expanded when the balloon **620** is inflated. This configuration allows for gas venting without obstructing the path of the acoustic beam **54** that radiates through an expandable portion **1202**.

[0066] FIG. **15** illustrates an anisotropic balloon **620** according to another embodiment that includes a distal tip having valve **1510** for venting or bleeding air from within the balloon. For example, the valve **1510** can be used to vent air from within the balloon **620** during initial filling of the balloon **620** with coolant fluid. FIG. **16** illustrates another embodiment of an anisotropic balloon **620** that includes both a vent tube **622** associated with an outer surface **621** of the balloon **620** and a vent valve **1510** at distal tip of the balloon **620** for releasing air from within the balloon **620**.

[0067] Referring to FIG. **17**, a probe body **610** according to one embodiment that may be used with an anisotropic balloon as shown in various figures includes a substantially rigid housing or shell **1702** that defines an open space or window **1704** for the transducer **622**. The distal end of the shell **1702** is configured for insertion into the balloon **610**. In the illustrated embodiment, the distal tip of the shell **1702** has a shape that generally corresponds to the distal tip of the balloon **620** so that the balloon **620** may be secured over or attached to the distal tip of the probe body **610**. Further, the balloon **620** can be attached to a proximal portion of the probe body **610**. For example, an inner surface of the balloon **610** can mate or interface with an outer surface of the probe body **610**. In this manner, the balloon **610**, while being expandable in at least one direction by inflation of portions **1204**, may be rigidly attached to the probe shell **1702** to prevent the balloon **610** from inflating into the rectal cavity.

[0068] The transducer **52** is housed within the shell **1702** and may be carried by the circuit board **625** or other suitable substrate. An example of a suitable circuit board **625** is illustrated in FIG. **18**. The circuit board **625** or other substrates or components carry deliver excitation or drive signals via wires or other connectors to individual elements **52***a*, **52***b*, . . . **52***n* of the transducer **52**.

[0069] The circuit board **625** or substrate is carried by a shaft **1905** (as further illustrated in FIG. **19**). The shaft **1905** and the transducer **52** carried thereby are rotatable within the shell **1702** in order to rotatably position the transducer **52** within the window **1704** when a procedure is to be performed, or away from the window **1704** to protect the transducer **52** or to prevent exposure to the transducer **52** during positioning of the probe **600** when the transducer **52** is not active. The assembly of the shaft **1905** carrying the circuit board **625**, which carriers the transducer **52**, is inserted into the shell **1702** of the probe body **610** as shown in FIG. **17**. The probe body shell **1702** and its components can then be inserted into the anisotropic balloon **610**, and the assembly of the balloon **610** and probe body **620** can then be inserted into the rectum **22**.

[0070] FIG. **19** also illustrates fluid or coolant ports **1910** and **1912**. A fitting **1920** provides a connection for a hose or other conduit for providing a cooling fluid through port **1910** formed in the shaft **1905** under the transducer **52** for cooling the transducer **52** and providing acoustic coupling. A fitting **1922** provides a connection for a hose or other conduit for withdrawing fluid through port **1912** formed at a distal end of the shaft **1905**. This arrangement provides sufficient fluid circulation and facilitates draining of air from within the balloon **620** during filling or inflation of the balloon **620** (e.g., using the balloon **620** having an air valve **1510** as shown in FIG. **15**).

[0071] Referring to FIG. **20**, a probe shell **1702** according to one embodiment includes a rotatable cover **2005** that can be positioned to encapsulate and protect the transducer **52**. According to one embodiment, the cover **2005** can be rotated by about 180 degrees to open and close the window **1704**. During use, the assembly of the anisotropic balloon **620** and the probe body **610** can be inserted into the rectum **22**, and

then the shaft **1905** can be rotated (e.g., 180 degrees) which, in turn, rotates the cover **2005** and transducer **52**, thereby opening the window **1704** and positioning and exposing the transducer **52** within the open window **1704** so that acoustic energy **54** emitted by the transducer **52** can be directed towards the prostate **16**.

[0072] According to one embodiment, the shell **1702** can be detached from the probe body **610** and discarded after each use, and a new shell **1702** can be applied to the probe body **610** for a new patient or other procedure. The shell **1702** can also have different dimensions depending on the anatomy of the particular patient to be treated, e.g., depending on the size of the rectum **22** and/or prostate **16** of the patient.

[0073] Although particular embodiments have been shown and described, it should be understood that the above description is not intended to limit the scope of embodiments since various changes and modifications may be made without departing from the scope of the claims. For example, embodiments can be implemented using various ultrasound transducers and other probe bodies. Further, embodiments can be implemented with one of multiple vent tubes, which can be various lengths while still being capable of venting gas. Additionally, vent tubes may be a separate component attached to a balloon or formed or made integral with the balloon. Further, although embodiments are described with reference to portions of an anisotropic balloon having different thicknesses, embodiments may also be implemented using portions composed of different materials that may also have different thicknesses so that portions have different elasticity and different degrees or rates of anisotropic expansion. Thus, embodiments are intended to cover alternatives, modifications, and equivalents that fall within the scope of the claims.

What is claimed is:

1. A transrectal ultrasound probe, comprising:
- a probe body carrying an ultrasound transducer;
- an anisotropic balloon member defining a cavity configured for receiving the probe body; and
- a tube associated with an outer surface of the anisotropic balloon member, the tube being configured for venting of rectal gas.

2. The probe of claim **1**, the ultrasound transducer being a focused ultrasound transducer for treating or ablating tissue.

3. The probe of claim **1**, the ultrasound transducer comprising an array of ultrasound transducer elements.

4. The probe of claim **1**, the probe body defining a window for the ultrasound transducer.

5. The probe of claim **4**, the probe body including a cover element that is rotatably positionable within the probe body to expose and cover the ultrasound transducer.

6. The probe of claim **1**, different portions of the anisotropic balloon member having different thicknesses.

7. The probe of claim **1**, wherein a thickness of middle portion of the anisotropic balloon member is less than a thickness of portions of the anisotropic balloon member adjacent the middle portion.

8. The probe of claim **7**, wherein the middle portion can expand more than the adjacent portions when the anisotropic balloon member is inflated.

9. The probe of claim **1**, further comprising a temperature sensor associated with the ultrasound transducer.

10. The probe of claim **9**, wherein the temperature sensor is not attached to the anisotropic balloon member.

11. The probe of claim **1**, the tube being attached to the outer surface of the anisotropic balloon member.

12. The probe of claim **1**, the tube being conformable to a shape of the anisotropic balloon member.

13. The probe of claim **12**, the tube being conformable to a non-linear outer surface of the anisotropic balloon member.

14. The probe of claim **1**, wherein no portion of the tube is positioned inside the anisotropic balloon member.

15. The probe of claim **1**, a distal end of the anisotropic balloon member defining a duct for venting air from within the anisotropic balloon member.

16. The probe of claim **1**, further comprising a location sensor associated with the transducer.

17. The probe of claim **16**, the location sensor including a plurality of magnetic resonance micro-coils.

18. A transrectal ultrasound probe, comprising:
- a probe body carrying an ultrasound transducer for treating or ablating tissue;
- a balloon member defining a cavity configured for receiving the probe body, wherein a thickness of a middle portion of the balloon member is less than a thickness of portions of the balloon member adjacent the middle portion;
- a tube conformable with an outer surface of the balloon member and being configured for venting of rectal gas; and
- a temperature sensor associated with the ultrasound transducer.

19. The probe of claim **18**, wherein the middle portion can expand more than the adjacent portions when the balloon member is inflated.

20. The probe of claim **18**, wherein the temperature sensor is not attached to the balloon member.

21. The probe of claim **18**, the tube being attached to the outer surface of the balloon member.

22. The probe of claim **18**, the tube being conformable to a non-linear outer surface of the balloon member.

23. The probe of claim **18**, wherein no portion of the tube is positioned inside the balloon member.

24. The probe of claim **18**, a distal end of the balloon member defining a duct for releasing air from within the balloon member.

25. A method of ablating tissue of a patient, comprising:
- inserting a probe into a rectum of the patient, the probe including a probe body carrying an ultrasound transducer, a balloon member defining a cavity configured for receiving the probe body, and a tube conformable with an outer surface of the balloon member;
- activating the ultrasound transducer; and
- ablating tissue using ultrasound energy emitted by the ultrasound transducer.

26. The method of claim **25**, further comprising venting gas in the rectum through the tube and outside of the patient.

27. The method of claim **26**, further comprising venting air from within the balloon member through a duct defined by a distal end of the balloon member.

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